



1280 '99 MMR 23 P2:15

March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

<u>Echinacea</u>: For healthy immune function. Echinacea supports the body's natural defenses and promotes general well-being especially during the winter months. No wonder so many people rely on Echinacea when cold weather hits. The ingredients in Sundown Echinacea XTRA support healthy immune function. This advanced formula features standardized Echinacea extract blended with an XTRA Premium Blend of Reishi and Shiitake Mushrooms, Astragalus and Goldenseal, which work in harmony to help promote healthy immune function.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs

and Assistant General Counsel

Deporate Show Anker

Enclosure